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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,186	09/28/2001	Jeffrey T. Ellis	50623.55	5975

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EXAMINER	
FOREMAN, JONATHAN M	
ART UNIT	**PAPER NUMBER**
3736	

DATE MAILED: 09/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/967,186	ELLIS ET AL.	
	Examiner	Art Unit	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/12/04 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3, 6, 7, 8, 14, 15, 24 and 25, are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 94/02845 to Wink et al. in view of U.S. Patent Application No. 2003/0028128 to Tenerz.

In reference to claims 1, 3, 6, 7, 8, 14, 15, 24 and 25, Wink et al. discloses a sensor with an electrically conductive substrate having an amperometric response that is unaffected by the presence of nitric oxide; and a coating for reacting with nitric oxide or superoxide so as to cause a change in the electrochemical potential of the nitric oxide (Page 7, line 31 – Page 8, line 2). The sensor comprises a catalytic material capable of oxidizing nitric oxide (Page 11, liens 6 – 24). Wink et al. discloses the sensor for detecting and/or measuring NO (nitric oxide) in vivo (Page 12, lines 5 – 9). However, Wink et al. fails to disclose the sensor being included in an elongated wire assembly

capable of being guided to a region of a vessel, the assembly having an elongated member including a lumen, and an opening in the elongated member in fluid communication with the vessel. However, Tenerz discloses an elongated wire assembly (Figure 6B) capable of being guided to a region of a vessel, the assembly having an elongated member including a lumen (61), and an opening (Figure 6B) in the elongated member, the opening positioned so the lumen is in fluid communication with the vessel. The sensor (44) is positioned within the lumen so that the sensor is in fluid communication with the vessel [0048]. It would have been obvious to one having ordinary skill in the art at the time invention was made to include the sensor as disclosed by Wink et al. in the elongated wire assembly as taught by Tenerz in order to investigate a physiological parameter inside the living body [0002] with a rotationally symmetric guidewire that is less prone to short circuiting [0016]-[0017].

4. Claims 1, 2, 4, 5, 7 – 9, 11, 13, 15 and 17 - 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent No. 6,112,598 to Tenerz et al.

5. In reference to claims 1, 2, 4, 5, 7 – 9, 11, 13, 15 and 17 – 25, Soller discloses an elongated assembly and a method using the elongated assembly comprising: positioning the elongated assembly into a designated region within a blood vessel (Col. 11, lines 16 – 19); measuring the level of nitric oxide (NO) in the region of the vessel (Col. 11, line 20); delivering a stimulant to increase the production of NO (Col. 11, lines 21 – 36); wherein the elongated assembly comprises a sensor having: a compound which can react with NO causing the optical properties of the compound to change; and an optical system for measuring the optical properties of the compound. Soller discloses the optical system including a first optic line for illuminating a light on the compound and a second fiber optic line to receive the light from the compound and to relay the received light to a

detector (Col. 8, line 36 – 56). Soller discloses the sensor comprising a catalytic material capable of oxidizing NO (Col. 10, lines 23 – 44). However, Soller fails to disclose the elongated assembly having an elongated member including a lumen, having an opening in the elongated member in fluid communication with the vessel and being configured to allow a catheter assembly to be disposed over a portion thereof. However, Tenerz et al. discloses an elongated assembly (Figure 2) having an elongated member including a lumen (21), having an opening in the elongated member in fluid communication with the vessel (Col. 5, lines 14 – 16) and being configured to allow a catheter assembly to be disposed over a portion thereof . The sensor is capable of bending away form a central longitudinal access of the core section (Col. 6, lines 43 – 48). It would have been obvious to one having ordinary skill in the art at the time invention was made to include the sensor as disclosed by Wink et al. in the elongated wire assembly as taught by Tenerz et al. in order to provide a free space surrounding the distal part of the sensor to accommodate the sensor when the assembly is subjected to bending (Col. 5, lines 39 – 47).

6. Claims 10, 12 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,582,170 to Soller in view of U.S. Patent No. 6,112,598 to Tenerz et al. as applied to claim 8 above, and further in view of U.S. Patent No. 5,945,542 to Cooke et al.

In reference to claims 10, 12 and 16, the method as disclosed by Soller in view of Tenerz et al. as discussed above fails to disclose the steps of inserting a catheter over the wire assembly, delivering the stimulant acetylcholine, and the designated region within the vessel being affected by restenosis. Cooke et al. discloses a method wherein an infusion catheter is advanced over a guide wire to infuse acetylcholine (Col. 18, lines 35 – 38). Cooke et al. teaches that administering acetylcholine diminishes the formation of atherosclerotic plaque and restenosis. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the

method as disclosed by Soller in view of Tenerz et al. to include the steps of advancing a catheter over the guidewire to administer the stimulant acetylcholine to an area of restenosis in a vessel as taught by Cooke et al. in order to diminish the formation of atherosclerotic plaque and restenosis by inhibiting adhesion of monocytes and platelets, and by reducing the proliferation of vascular smooth muscle cells (Col. 18, line 63 – Col. 19, line 3).

Response to Arguments

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,345,932 discloses a sensor assembly for penetrating into a vessel having a sensor located in a lumen of an elongated member, an opening in the elongated member to allow the sensor to be in fluid communication with the vessel in which it is inserted.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (703) 305-5390. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703)308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JMLF

MAX F. HINDENBURG
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